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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,318

Applicant(s)

ALDAZ ET AL.

Examiner

Sheela J Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8-12,15,18-26,29,32,33,36 and 39 is/are rejected.
- 7) ☒ Claim(s) 74-81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6,7,13,14,16,17,27,28,30,31,34,35,37,38 and 40-73.

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DETAILED ACTION

Response to Amendment

The amendment filed on 9/27/04 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-81 are pending.

Claims 1-2, 5, 8-12, 15, 18-26, 29, 32-33, 36, 39 and 74-81 are currently under consideration.

Claims 3-4, 6-7, 13-14, 16-17, 27-28, 30-31, 34-35, 37-38, 40-73 are withdrawn from consideration as being drawn to a non-elected invention.

The objection to the specification is withdrawn.

The rejection of the claims under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments.

The rejection of the claims under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

The rejection of claims 1-2, 5 and 8-10 under 35 U.S.C. 102(a) as being anticipated by Bednarek et al Cancer Research vol. 60 p. 2140 (4/00) is withdrawn in view of the Katz declaration.

The art rejections over WO 01/44466 are withdrawn in view of applicant's arguments.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 8-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/12544 (priority to 8/7/00). The reasons for this rejection are of record in the paper mailed 6/22/04.

Applicant argues that the Katz declaration provides sufficient evidence that the application was not filed before the invention by applicant. The Katz declaration provides evidence that the authors listed on the reference, other than those listed on this application, were involved in the conception of the instant invention.

New Grounds of Rejection

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

Applicant's change on page 5, line 3 results in the sentence reading as follows: "the polynucleotide comprises a nucleic acid sequence included in SEQ ID NO:2, SEQ ID NO:31, or SEQ ID NO:33". These sequences are amino acid sequences not nucleic acid sequences.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 8, 18 refers to 50 contiguous amino acids. This is not found in the specification. Page 56 only refers to 90 and 150 contiguous amino acids.

Claim Rejections - 35 USC § 112

Claims 1, 11, 25 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The terminology "at least 20 contiguous amino acids" is new matter. Page 56 of the specification does not show "20".

Claims 1-2, 5, 8-12, 15, 18-26, 29, 32-33, 36, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a polynucleotide comprising a nucleic acid sequence encoding at least [20, 50, 150] contiguous amino acids of SEQ ID NO. 2 or encoding a sequence having at least 90% to Seq ID No. 2 or 99% identity to SEQ ID No. 1.

While the amino acid sequence of SEQ ID NO:2 and the nucleic acid sequence of SEQ ID No. 1 are adequately described in the specification as-filed, thereby providing an adequate basis for those sequences; there is insufficient written description as to the identity of a polypeptide having at least 90-99% sequence identity to SEQ ID NO:2 that would still maintain the function of the polypeptide or to a sequence that has 99%

identity to SEQ ID NO. 1 or a nucleic acid encoding at least [20, 50, 150] contiguous amino acids of SEQ ID NO. 2 that would still maintain the function of the polypeptide.

The specification as filed does not provide adequate written description support for a polynucleotide comprising a nucleic acid sequence encoding at least [20, 50, 150] contiguous amino acids of SEQ ID NO. 2 or encoding a sequence having at least 90% to Seq ID No. 2 or 99% identity to SEQ ID No. 1.

First, polypeptides having diverse functions are encompassed by the phrase 90-99% identity. Thus a broad genus having potentially highly diverse functions is encompassed by the phrase 90-99% sequence identity” and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. For example, Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., “Abstract” and “Sequence-based approaches to function prediction”, page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan’s best guess as to the function of the structurally related protein (see in particular “Abstract” and Box 2).

Second, applicant has not adequately described structure that is located on either side of a polynucleotide comprising a nucleic acid sequence encoding at least [20, 50, 150] contiguous amino acids of SEQ ID NO. 2. There is no description as to where the functional domains are within SEQ ID NO. 2 and if these domains are to

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included in the [20, 50, 150] contiguous amino acids. Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Therefore, only SEQ ID No. 2 meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Allowable Subject Matter

Claims 74-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sheela J Huff
Primary Examiner
Art Unit 1642

sjh